



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

May 1, 2003

**WARNING LETTER NYK 2003-24**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

James S. Lipiec  
453 Bellinger Road  
Little Falls, New York 13365

Dear Mr. Lipiec:

An investigation conducted on February 27 and March 11, 2003 by U.S. Food and Drug investigator Bruce G. Cooper at your dairy operation located in Little Falls, New York confirmed that in January 2003 you offered a cow for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed you caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about January 16, 2003, you sold a cow identified with farm tag number 21ZET5733 for slaughter as human food. The cow was later slaughtered at [REDACTED] USDA analysis of a tissue sample collected from that animal on January 17, 2003 at [REDACTED] identified the presence of the drug penicillin at a level of 0.13 parts per million (ppm) in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (*Title 21 Code of Federal Regulations* (21 CFR), Part 556.510). The presence of this drug at the level reported in edible tissue from this animal causes the food to be adulterated with the meaning of Section 402(a)(2)(C)(ii) of the Act.

In addition, you caused the drug [REDACTED], a brand of penicillin, which you use on dairy cows, to become adulterated within the meaning of Section 501(a)(5) when you failed to use the drug in conformance with its approved labeling. Your use of this drug in dairy cows without following the recommended dosage and administration instructions on the label causes the drug to be unsafe and, therefore, adulterated.

You should not consider this letter to be an all-inclusive list of violations existing at your facility. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

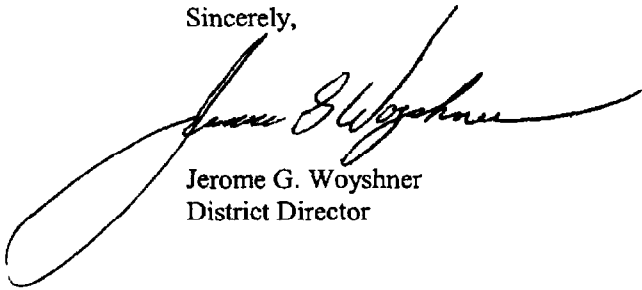
It is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was subsequently offered for sale to a slaughterhouse which ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

James S. Lipiec  
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You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action being initiated by FDA without further notice. This may include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step you have taken or will take to correct the violations and to prevent the recurrence of similar violations. Your response should be directed to Lisa M. Utz, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", with a large, sweeping loop at the end.

Jerome G. Woyshner  
District Director